DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

95186

JAN 10 2005

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Neil E. Carden, Managing Director
Arjo Med. AB Ltd.
St. Catherine Street
Gloucester, GL1 2SL, United Kingdom

Dear Mr. Carden:

During an inspection of your firm located in Gloucester, United Kingdom on August 2, 2004 through August 6, 2004, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures AC-powered patient lifts, non-AC-powered patient lifts, and transfer chair aid devices. These products are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321(h)).

This inspection revealed that these devices appear to be adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. Significant violations include, but are not limited to, the following:

1. Failure to validate with a high degree of assurance a process that cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a).

    a. Opera and Tempo patient lifts require welding on the [redacted] Chassis Cross Member. Your firm could not produce the validation report for the welding process.

    b. Your firm conducts load, tensile, and bending tests for a specific time duration on Attachment Clips, Part Numbers [redacted] and [redacted]. Your firm could not provide any specific rationale

for why the test durations were long enough or how they were derived.

2. Failure to adequately establish and maintain procedures for implementing corrective and preventive action, which include requirements for analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential problems, as required by 21 CFR 820.100(a)(1). For example, your firm failed to apply statistical analysis for concessions, nonconformance, and rework. Additionally, the Quality Assurance Procedure (QAP) 052, Corrective and Preventive Actions, does not provide for adequate analysis of quality data sources, in that your firm has broken down the CAPA responsibilities into various managerial groups. Section 5.0 (Responsibilities) of QAP 052 states the individual responsibilities of various positions; however, there does not appear to be any system-wide analysis of CAPA issues. Section 6.0 (CAPA Procedures) of QAP 052, does not state that any analysis of quality data sources is to be conducted.

3. Failure to adequately establish and maintain procedures for implementing corrective and preventive action, which include requirements for verifying or validating the corrective action to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4). For example, your firm initiated CAPA, [redacted], which included the addition of a [redacted] to a printed circuit board (PCB); however, the firm failed to provide evidence of adequate verification or validation of the CAPA prior to implementing the CAPA into manufacturing/distribution. Additionally, Section 6.0 (CAPA Procedures) of QAP 052 does not state that corrective and preventive actions are to be verified or validated in order to ensure that such actions are effective and do not adversely affect the finished device.

4. Failure to adequately establish and maintain procedures for implementing corrective and preventive action, which include requirements for ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems, as required by 21 CFR 820.100(a)(6). For example, QAP 052 does not adequately ensure that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems.

5. Failure to adequately establish and maintain procedures for implementing corrective and preventive action, which include requirements for submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review, as required by 21 CFR 820.100(a)(7). For example, Section 6.0 (CAPA Procedures) of QAP 052 does not state that relevant information for identified quality problems, as well as corrective and preventive actions, is to be submitted for management review.

6. Failure to develop documented instructions, standard operating procedures, and methods that define and control the manner of production, as required by 21 CFR 820.70(a)(1). For example, your firm's written assembly instructions for the Opera are inadequate in that they fail to provide step-by-step instructions on how to assemble the Opera patient lift.

7. Failure to establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained, as required by 21 CFR 820.72. For example, Test Rig [redacted] is required to be calibrated every [redacted] A review of the calibration records for this tool shows that your firm has been calibrating this tool only once [redacted] beginning in April 1994 through December 2003.

8. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. For example, your firm had a

subcontractor [redacted] which were to be used in the rework of 98 Tempo brand patient lifts. After distribution, one of the lifts failed after a pin seized in the pivot assembly of the spreader bar, which caused an MDR reportable event. Your firm stated that the failure was due to a spacer being improperly reamed, which caused an interference fit and the subsequent MDR reportable event.

9. Failure to maintain adequate device master records, as required by 21 CFR 820.181. For example, the device master records (DMR) for the Tempo and Opera brand patient lifts did not include or refer to the location of all required documentation including: production procedures; equipment specifications; packaging procedures; and labeling specifications.

This letter is not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Given the serious nature of these violations of the Act, non-AC-powered patient lifts, AC-powered patient lifts, and transfer aid chairs manufactured by your firm and imported or offered for import are subject to refusal of admission under section 801(a) of the Act, 21 U.S.C. § 381(a), in that they appear to be adulterated. As a result, FDA may take steps to refuse these products, known as "detained without physical examination," until these violations are corrected.

In order to remove the devices from detention, you should provide a written response to this Warning Letter as described below and correct the violations described in this letter. We will notify you if your response is adequate, and we may need to re-inspect your facility to

verify that the appropriate corrections have been made. In addition, U.S. federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of government contracts.

We received a response from Mr. Geoff Hogg, Quality Assurance Director, dated September 17, 2004, concerning our investigator's observations noted on the FDA 483. We have reviewed your response and have concluded that it is inadequate. Our detailed comments to your response have been communicated to you via separate letter dated, December 20, 2004.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter, of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include all documentation of the corrective action you have taken. If you plan to make any corrections in the future, include those plans with your response to this letter as well. If the documentation is not in English, please provide a translation to facilitate our review.

Please direct your response to Carolyn Niebauer, Chief, General Hospital Devices Branch, HFZ-333, Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, MD 20850. If you have any questions about the contents of this letter please contact Ms. Niebauer at (240) 276-0115 or by facsimile at (240) 276-0114.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health